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GMP

Degania Silicone Ltd.

Degania Bet 15130, Israel. Tel: 972-6-755712, Fax: 972-6-709182

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K964547

APPENDIX E510(k) SUMMARY

Trade Name: Degania Silicone Identi Loops

Common Name: Vascular Ties or Loops

Product Code: 79

Device Class: I

Classification Panel: General & Plastic Surgery

Establishment Registration Number: 8030107

This summary of 510K safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807:92.

DEVICE DESCRIPTION AND USE:

The Identi Loops are designed and indicated for temporary intraoperative use during various general surgical procedures requiring identification, retraction, or occlusion of tendons, ureters, nerves, arteries or veins. The Identi Loop is not designed nor indicated for Implantation.

Previously 2 sizes Mini and Maxi were available, we have now added Super Maxi (Extra Maxi).

MANUFACTURING:

The Identi Loops are manufactured from the same raw materials, from the same vendors and using the same manufacturing processes as our previous 510(k).

SUBSTANTIAL EQUIVALENCE:

We are Substantially Equivalent to ourselves.

Bette Lubin
Product Advisor &
Regulatory Affairs
Degania Silicone

Nov. 11, 1996

Date

24/25